



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 12 2000

4 8 5 8 '00 JAN 28 P2:37

Dr. Dennis Jones
Herbal Science, Inc.
40 Allen Road
South Burlington, Vermont 05482

Dear Dr. Jones:

This is in response to your letter of January 3, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Herbal Science, Inc. is making the following claim, among others, for the product **ZHIshape™**:

“...has been shown to have mild anti-depressive activity...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely, depression. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New England District Office, Office of Compliance, HFR-NE240

975-0163

LET 326

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

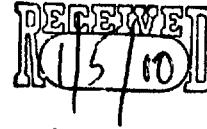
HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:1/11/00:docname:68676.adv:disc43

**Notification of a Structure/Function Statement, FDCA § 403(r)(6);
21 U.S.C. § 343(r)(6).**

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., SW.
WASHINGTON, DC 20204



Packer: Herbal Science Inc.
40 Allen Road
SOUTH BURLINGTON, Vermont 05482

Tel: (802) 862-9139
Fax: (802) 862-0820

Text: Bitter Orange (*Citrus aurantium*) contains small amounts of alkaloids such as synephrine and octopamine, which are direct- and indirect-acting adrenergic agents. Adrenergic agents with β -agonist activity stimulate lipolysis and increase the resting metabolic rate in some persons, thus increasing the removal and oxidation of fat from adipose tissue stores. This action is potentiated by methylxanthines, such as caffeine, present in Guarana (*Paullinia cupana*). St. John's Wort (*Hypericum perforatum*) contains the substance hypericin, which has been shown to have mild anti-depressive activity and is believed to modify serotonin levels in the brain with consequent effects on satiety. **These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

Name of Dietary Supplement: ZHishape™.

(Herbal Science, Inc., South Burlington, VT 05403)

I hereby certify that the information contained in this notification is complete and accurate, and that there is substantiation that the statement is truthful and not misleading.

Dr. Dennis Jones,
M.A., Ph.D., C.Chem., FRSC(UK)
MCIC, C.Biol., M.I.Biol., MBIM.

3 January, 2000.